

a positive recitation of function and is indefinite ;that claims 23 and 24 recite the method of claim 22, which is an apparatus claim; that in claims 25-31 it is unclear what further structure is to be claimed; that the "sensor means" of claim 33 lacks positive recitation function; that in claim 35 the "treating..." steps appears redundant in view of the "transferring..." and "releasing..." steps, and that in claims 36-52 it is unclear what further method step is claimed. Office action mailed 1/14/99, 2:1-2.

The examiner has stated that "in claim 1 the meaning of the term 'surface n contact' is unclear." Claim 1 has been amended to change the term "surface n contact" to "surface in contact" support for which is found in the specification and claims as originally filed. This now describes that the energy delivery surface of the energy source is in contact with the skin surface to be treated. Accordingly, withdrawal of this rejection is respectfully requested.

The examiner has raised a question of "what further method steps the recited structure in claims 2-13 is supposed to imply". Claims 2-12 further refine the method of claim 1, and as such, are considered allowable. For example, claims 4-6 provide a further refine to the step of "providing an energy source with an energy delivery surface". Similar refinements were allowed in dependant method claims 3, 5 and 6 of US Patent No. 5,843,071 which provided recitation of structure only. Also, claim 13 has been amended to include the step of "partially denaturing the collagen containing tissue site by cleaving heat labile cross-links of collagen molecules." Support for this amendment is found on page 12, lines 11-12. Accordingly, withdrawal of this rejection is respectfully requested.

The examiner has taken the position that in claim 22 "the electrolytic media means and RF electrode means lack a positive recitation of function." Claim 22 has been amended to include a recitation of the function of the RF electrode to be a transfer of energy and the function of the electrolytic media to be the delivery of energy. Support for these amendments is found in the claims as originally filled, specifically claim 29, lines 1-3; and claim 35, lines 5-6. The examiner has also taken the position that sensors means lacks a positive recitation of function. Claim 33 has been amended to recite the function of the sensor means to be measurement of a thermal property. Support for this amendment is found on page 9, lines 21-22. Accordingly, withdrawal of this rejection is respectfully requested.

The examiner has taken the position that the "treating" step in claims 35 appears redundant in view of the preceding "transferring" and "releasing" steps. Applicant respectfully calls to the examiner's attention that the preceding steps refer to the transferring of energy to the electrolytic media and then releasing of the media to the skin. Up to this point, treatment has not occurred because energy has not been delivered to the skin surface. Thus the treating step is a separate, distinct and hence definite step and not redundant to any of the preceding steps. Accordingly, withdrawal of this rejection is respectfully requested.

The examiner has also taken the position that "There is no disclosure of a means for detecting a wrinkle." Applicant respectfully disagrees and calls examiner's attention to page 9, lines 17-18. These lines disclose the use of visualization, ultrasound, temperature and impedance for obtaining feedback to perform the procedure. All of these methods can be used by the skilled artisan to analyze features on a surface. Accordingly, withdrawal of this rejection is respectfully requested.

The examiner has raised the question in claims 36-52 "what further method step is claimed". Claims 36-52 further refine the method of claim 35, and as such, are considered allowable. Similar refinements were allowed in claims 4-7 of US Patent 5,282,797. Accordingly, withdrawal of this rejection is respectfully requested.

#### Rejections under 35 U.S.C. 102

Claims 22-34 stand rejected under 35 U.S.C. §102(e) as being clearly anticipated by Eggers '909, et al. Office action mailed 1/14/99, 9:1-3.

Applicant respectfully traverses this rejection. The method of the present invention for reducing a the depth of a wrinkle provides an energy source with an energy delivery surface that is positioned in contact with the skin surface. Energy is delivered through the skin surface to the collagen containing tissue. A reverse thermal gradient is created, in which the temperature of the skin surface is less than the temperature of the collagen containing tissue. At least a portion of the collagen containing tissue is contracted with controlled cell necrosis and a depth of the wrinkle is reduced. Eggers '909 teaches away from the current invention in that the apparatus taught in Eggers '909 is configured for ablating and cutting tissue whereas the present

invention is not. These intended functions of Eggers '909 are described in the title, abstract and summary of the invention ( lines 56-57 of column 2). This distinction in function is further evidenced by several structural difference between Eggers '909 and the present invention. The present invention has an electrolytic media delivery means (claims 22-34), Eggers '909 does not (while it does have a porous insulating layer, this layer is not configured for nor can it be used to deliver electrolytic media). Specifically, Eggers '909 has electrodes projecting from the distal probe tip and/or in direct contact with tissue. In contrast, the present invention has the electrode separated from the skin surface (claim 25) and has the electrode positioned in an interior of the contact with the tissue and has the electrodes recessed in the membrane (claim 26). The skilled artisan would not be motivated to make any modifications to Eggers '909 , because to do so would reduce the current density/flux at the Eggers '909 electrode which is in direct contradiction to "A central aspect of the .... (Eggers) invention is the ability of the probe 10 to deliver high energy flux levels" (Col 12). In fact, reducing this current density would actually render Eggers '909 unsatisfactory for its intended purpose: " the cutting of body structures" including "the rapid cutting of body structures". Moreover, one of the key stated improvements of Eggers '909 over the prior art is its ability not to have energy dissipation from its electrodes which is described as significantly reducing the capability to cut or ablate tissue (column 12, lines 29-35). Accordingly, withdrawal of this rejection is respectfully requested.

Additionally, new claims 61-69 require a porous membrane with low porosity zones and/or a focusing element neither of which is taught or suggested in Eggers '909 . Therefore, claims 61-69 are considered independently patentable. Support for the use of "porous membrane" in claims 61-69 is specifically found on page 4 lines 23-25; page 8, lines 1-11; and page 9 line 4-8. Support for the use of "zones of decreased porosity" in claims 63-64 is found on page 10, lines 7-12. Support for the use of "a focusing element" in claims 65-69 found on page 10, lines 26-28.

#### Rejections under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-21 and 35-60 as being obvious over Neeffe in combination with Sand 709'. The Examiner states that Neeffe teaches a method as claimed except for cooling the surface and that Sand teaches the

desirability of providing surface cooling to control damage to the surface when treating underlying tissues, and that it would have been obvious to employ various forms of energy of Neeffe in the method of Sand, thus producing the claimed method. Office action mailed 1/14/99, 8:3-4.

The examiner has rejected claims 1-21 and 35-60 as being unpatentable over Neeffe ('230) in view of Sand ('709). Specifically, the examiner has taken the position that "Neeffe teaches a method as claimed except for cooling the surface." Applicant respectfully disagrees and points out that Neeffe does not teach all steps of the present invention and actually teaches away from the invention. First, Neeffe does not teach delivery of energy to the skin surface, but rather the cornea. There are significant anatomical, morphological, mechanical and thermodynamic differences between the skin surface and the cornea (e.g. thermal diffusivity, avascular nature of the cornea, thickness, etc) which render the methods taught by Neeffe wholly unsuitable for treatment of the skin. Moreover, these difference are so significant so as to require the skilled artisan to engage in undue experimentation in order to modify them for treatment of the skin if such modification is possible at all. Another key distinction requiring undue experimentation is the fact that the cornea is supported/connected on its entire perimeter by the sclera. The present invention does not necessarily include such a limitation and owing to Bessel function and other constraints, the collagen contraction occurring in Neeffe would be expected to be significantly different from the collagen contraction of tissue in the present invention not so supported. As a result of one or more of these differences, there would be no degree of predictability in combining Neeffe with Sand to practice the current invention and no expectation of success.

Second Neeffe does not provide "an energy source with an energy delivery surface" as the present invention does. None of the energy sources recited by Neeffe include the recitation of an accompanying energy delivery surface. Instead, Neeffe teaches an indirect form of energy delivery by heating a mold in vitro and then transferring the mold to the cornea. The mold can not be considered an energy source since all energy must be transferred to it, hence it is an energy sink not a source. Moreover, while Neeffe may claim a method for heating the metal mold in situ, it does not disclose a specific technique or method for doing so. Owing to the complex heat transfer considerations involved, combined with the significant safety

constraints of not injuring the eye, such knowledge was not known to the skilled artisan and in this respect, Neeffe is not enabled.

Also, Neeffe is incapable of producing a reverse thermal gradient as is claimed in the present invention even when combined with cooling. This is because Neeffe only teaches the delivery of energy to tissue from a heated mold placed on the cornea (tissue) surface. The only form of appreciable energy delivery to the surface under this circumstance is by thermal conduction. Owing to Fourier's law governing conductive heat transfer, a reverse thermal gradient can not be created for conduction alone even with the presence of simultaneous cooling. That is, both heating by conduction and cooling by conduction travel at the same rate through tissue. Thus the combination of cooling taught by Sand ('709) with Neeffe will render Neeffe incapable of performing its ordinarily intended function since cooling will directly offset any heating at the intended tissue treatment site. Therefore, the skilled artisan would have no expectation of success in combining Neeffe with Sand ('709).

Also, Neeffe does not also teach the use of electrolytic media or RF energy as described in independent claims 22 and 35. Neeffe does not specifically recite the use of RF energy or the transfer of energy from an RF electrode to electrolytic media. The only form of energy delivery to a tissue surface that Neeffe teaches is thermal conduction. All other forms of energy recited by Neeffe are used to heat the mold and not the tissue.

Also, Neeffe does not teach or suggest contraction of collagen with "controlled cell necrosis" as is taught in independent claims 1, 22 and 35. Neeffe only teaches contraction of collagen. Since Neeffe only uses the externally heated mold to deliver energy Neeffe is incapable of having the necessary control of energy delivery to produce such a controlled cell necrosis. Moreover, owing to Neeffe's limited ability to only deliver energy by the heated mold, e.g. conduction, combined with the complex heat transfer consideration involved it would not be obvious to the skilled artisan how to modify the method taught by Neeffe to produce such a controlled cell necrosis. The difficulty in doing so is compounded by the significant difference in anatomy, morphology and thermal properties between the cornea and the skin and underlying fat tissue. As describe above, such difference include the fact the cornea is avascular, has a different thermal diffusivity, composition and thickness verses the skin.

Finally, Neeffe may lack enabling disclosure because the mold disclosed in Neeffe is not configured to apply adequate force onto the cornea of the eye to achieve the reshaping effect. Research has shown the cornea is extremely strong with a Young's (elastic) modulus of the cornea to be greater 725 lbs/(inch<sup>2</sup>) or  $5 \times 10^6$  Newtons/m<sup>2</sup>. This means to displace the cornea even 0.01<sup>2</sup> inches requires the application of 7.25 lbs of force. Neeffe does not teach the application of this or any external force to cornea including the inclusion of any examples. The only force that would be applied to the cornea would be a passively applied force due to the weight of the mold on the eye which would could not realistically be greater than several grams (e.g. five grams or 0.01 lbs). Even accounting for softening that may occur as a result of heating or chemical treatment displacement it seems unlikely that the cornea would soften by the several orders of magnitude necessary to allow the weight of the mold alone to cause even minor deformation. Moreover, Neeffe does not disclose or provide any examples of how much softening does occur so the skilled artisan is left guessing. Also Neeffe does not disclose any example of how much external force to apply to the cornea in order to achieve a desired amount of corneal deformation, or how the force should be applied. This information is critical to the function of Neeffe yet absent. Owing to skill in the art at the time, the elucidation of such information would have required the skilled artisan to engage in substantial undue experimentation. While Neeffe does mention the use of intraocular pressure to push the cornea into the mold, this approach is critically flawed because: 1) Neeffe does not teach the use of an externally applied force to hold the mold in place to counter the interocular force, 2) Neeffe does provide working examples or data to prove that this force is sufficient 3) the interocular force is insignificant compared to the forces necessary to deform the cornea. Because of this lack of enablement, together with the other deficiencies discussed herein the skilled artisan would not and could not use Neeffe in combination with Sand to practice the current invention. For these and the reason described above, withdrawal of this rejection is respectfully requested.

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Provisional Rejections under Judicially Created Doctrine  
of Obviousness-Type Double Patenting

The Examiner has provisionally rejected the following claims under the judicially created doctrine of obviousness-type double patenting over the commonly owned applications as set forth below:

claims 1-21 and 35-60 over claims 1-44 of co-pending app 09/003,120;  
claims 1-21 and 35-60 over claims 1-27 and 41-68 of co-pending app 09/003,098;  
claims 1-21 and 35-60 over claims 1-34 and 56-89 of copending app 09/003,180;  
claims 1-21 and 35-60 over claims 55-65 of copending app 08/942,274;  
claims 1-21 and 35-60 over claims 31-54 of copending app 08/990,494;  
claims 1-21 and 35-60 over claims 1-3, 5-10, 12-13, 15-29 of copending app 8/825,443;  
claims 1-21 and 35-60 over claims 1-8, 12-14, 16-20, 55-61 of copending app 8/583,815;  
claims 22-34 over claims 1, 3-4, 12-14, 21-29, 35-38, 46-60 of copending app 08/827,237;  
claims 22-34 over claims 28-40 of copending app 09/003,098;  
claims 22-34 over claims 35-55 of copending app 09/003,180;  
claims 22-34 over claims 1-54 of copending app 08/942,274; and  
claims 22-34 over claims 1-30 of copending app 09/990,494.

Applicant submits terminal disclaimers to overcome the examiner's objections.

CONCLUSION

It is submitted that the present application is in form for allowance, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 16904-726). A duplicate copy of this paper is enclosed.

Respectfully submitted,

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